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�54 Shape memory alloys.

㊼ Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

EP 0 145 166 A2

DESCRIPTION

SHAPE MEMORY ALLOYS

This invention relates to medical devices incorporating
shape memory alloys, and to improvements therein.

Materials, both organic and metallic, capable of
possessing shape memory are well known. An article
5   made of such materials can be deformed from an original,
heat-stable configuration to a second, heat-unstable
configuration. The article is said to have shape
memory for the reason that, upon the application of
heat alone, it can be caused to revert, or to attempt
10   to revert, from its heat-unstable configuration to its
original, heat-stable configuration, i.e. it "remembers"
its original shape.

Among metallic alloys, the ability to possess shape
memory is a result of the fact that the alloy undergoes
15   a reversible transformation from an austenitic state to
a martensitic state with a change in temperature. This
transformation is sometimes referred to as a thermo-
elastic martensitic transformation. An article made
from such an alloy, for example a hollow sleeve, is
20   easily deformed from its original configuration to a
new configuration when cooled below the temperature at
which the alloy is transformed from the austenitic
state to the martensitic state.

The temperature at which this transformation begins is
25   usually referred to as M_s and the temperature at
which it finishes M_f. When an article thus deformed

is warmed to the temperature at which the alloy starts
to revert back to austenite, referred to as A_s (A_f
being the temperature at which the reversion is complete)
the deformed object will begin to return to its original

5   configuration.

Many shape memory alloys (SMAs) are known to display
stress-induced martensite (SIM). When an SMA sample
exhibiting stress-induced martensite is stressed at a
temperature above M_s (so that the austenitic state is

10   initially stable), but below M_d (the maximum temperature
at which martensite formation can occur even under
stress) it first deforms elastically and then, at a
critical stress, begins to transform by the formation
of stress-induced martensite. Depending on whether the

15   temperature is above or below A_s, the behavior when
the deforming stress is released differs. If the
temperature is below A_s, the stress-induced martensite
is stable; but if the temperature is above A_s, the
martensite is unstable and transforms back to austenite,

20   with the sample returning (or attempting to return) to
its original shape. The effect is seen in almost all
alloys which exhibit a thermoelastic martensitic
transformation, along with the shape memory effect.
However, the extent of the temperature range over which

25   SIM is seen and the stress and strain ranges for the
effect vary greatly with the alloy.

In U.S. Patent Application No. 541844, the disclosure of
which is incorporated herein by reference, a nickel/
titanium/ vanadium alloy having SIM over a wide tem-

30   perature range is disclosed.

Shape memory alloys have found use in recent years in,
for example, pipe couplings (such as are described in
U.S. Pat. Nos. 4,035,007 and 4,198,081 to Harrison and
Jervis), electrical connectors (such as are described
5   in U.S. Pat. No 3,740,839 to Otte & Fischer), switches
(such as are described in U.S. Patent No. 4,205,293),
actuators, etc.

Various proposals have also been made to employ shape
memory alloys in the medical field. For example, U.S.
10   Pat. No. 3,620,212 to Fannon et al. proposes the use of
an SMA intrauterine contraceptive device, U.S. Pat. No.
3,786,806 to Johnson et al. proposes the use of an SMA
bone plate, U.S. Pat. No. 3,890,977 to Wilson proposes
the use of an SMA element to bend a catheter or cannula,
15   etc.

These medical SMA devices rely on the property of shape
memory to achieve their desired effects. That is to
say, they rely on the fact that when an SMA element is
cooled to its martensitic state and is subsequently
20   deformed, it will retain its new shape; but when it is
warmed to its austenitic state, the original shape will
be recovered.

However, the use of the shape memory effect in medical
applications is attended with two principal disadvantages.
25   First, it is difficult to control the transformation
temperatures of shape memory alloys with accuracy as
they are usually extremely composition-sensitive,
although various techniques have been proposed (including
the blending by power metallurgy of already-made alloys
30   of differing transformation temperatures: see U.S.
Pat. No. 4,310,354 to Fountain et al.). Secondly, in
many shape memory alloys there is a large hysteresis

as the alloy is transformed between austenitic and
martensitic states, so that reversing of the state of
an SMA element may require a temperature excursion
of several tens of degrees Celsius. The combination of

5   these factors with the limitation that (a) it is
inconvenient to have to engage in any temperature
manipulation, and (b) human tissue cannot be heated or
cooled beyond certain relatively narrow limits
(approximately 0° - 60°C for short periods) without

10   suffering temporary or permanent damage is expected to
limit the use that can be made of SMA medical devices.
It would thus be desirable to develop a way in which
the advantageous property of shape memory alloys,
i.e. their ability to return to an original shape after

15   relatively substantial deformation, could be used in
medical devices without requiring the delicacy of
alloying control and/or the temperature control of
placement or removal needed by present shape memory
alloy devices.

20   We have discovered that if, in a medical device
containing a shape memory alloy element which uses the
shape memory property of that alloy, an element which
shows the property of stress-induced martensite is used
instead, an improved device results.

25   Accordingly, a first aspect of the present invention
provides a medical device intended for use within a
mammalian body, or in such proximity to a mammalian
body that the device is substantially at body
temperature, which device comprises an alloy element

30   which displays stress-induced martensite at said body
temperature.

The device according to the present invention may, for example, be used as a heart valve, a catheter, for example a tracheal catheter, an intrauterine contraceptive device, a bone plate, a marrow nail, a dental arch

5   wire, a bone staple, or a clip.

A second aspect of the present invention provides a method of installing a pseudoelastic shape-memory alloy medical device within a mammalian body, or in such proximity to a mammalian body that the device is

10   substantially at body temperature wherein the pseudo-elastic shape-memory alloy medical device displays reversible stress-induced martensite at body temperature, the method comprising:

         deforming the medical device into a deformed shape

15   different from a final shape, said deforming
         occurring by the formation of stress-induced
         martensite;

         restraining the deformed shape of the medical
         device by the application of a restraining means;

20   positioning the medical device and restraining
         means within, or in proximity to, the body;

         removing the restraining means;

         isothermally transforming the device from the
         deformed shape into the final shape.--

25   A third aspect of the present invention provides a method of installing a medical device within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, the method comprising:

manufacturing the medical device from a pseudo-
elastic shape-memory alloy wherein the pseudoelastic
shape-memory alloy medical device displays
reversible stress-induced martensite at body

5   temperature;

deforming the medical device into a deformed shape
different from a final shape, said deforming
occurring by the formation of stress-induced
martensite;

10   restraining the deformed shape of the medical
device by the application of a restraining means;

positioning the medical device and restraining
means within, or in proximity to the body;

removing the restraining means;

15   isothermally transforming the device from the
deformed shape into the final shape.--

A fourth aspect of the present invention provides a
medical device assembly for use within a mammalian
body or in such proximity to a mammalian body that the

20   medical device is substantially at body temperature,
comprising:

a medical device and a restraining means;

said medical device being made of a pseudoelastic
shape-memory alloy displaying reversible,

25   stress-induced martensite at body temperature;

said medical device being deformed by the formation
of stress-induced martensite into a shape different
from a final shape and then restrained in the
deformed shape by said restraining means;

5   said medical device and said restraining means
being positioned in the body whereupon the
restraining means is removed and the medical
device isothermally transforms from the deformed
shape into the final shape.

10 The invention will now be described, by way of example,
with reference to the accompanying drawings, wherein:

Figures 1 and 2 illustrate the stress-strain behavior
of an alloy which exhibits constant stress versus
strain behavior due to stress-induced martensite.

15 The invention will be discussed first by introducing
the concept of stress-induced martensite and the effect
achievable by its use, and then by examples showing how
SIM alloy elements can be substituted for conventional
SMA elements in medical devices to achieve the beneficial
20 effect of the invention.

The Figures illustrate the phenomenon of stress-
induced martensite by means of stress-strain curves.
In both Figure 1 and Figure 2, the alloy is at a
temperature between M_s and M_d so that it is initially
25 austenitic; and it will be assumed for the puposes of
this discussion that M_s is equal to M_f, and A_s
equal to A_f. Figure 1 shows the case when the
temperature is below A_s, so that any martensite
formed by the applied stress is stable; while Figure 2
30 shows the case where the temperature is above A_s,
so that austenite is the only stable phase at zero
stress.

In Figure 1, when a stress is applied to the alloy,
it deforms elastically along the line OA. At a critical
applied stress, σ_M, the austenitic alloy begins to
transform to (stress-induced) martensite. This trans-
5   formation takes place at essentially constant stress
until the alloy becomes fully martensitic at point B.
From that point on, as further stress is applied, the
martensite yields first elastically and then plastically
(only elastic deformation is shown at point C). When
10   the stress is released, the martensite recovers
elastically to point D, at which there is zero residual
stress, but a non-zero residual strain. Because the
alloy is below A_s, the deformation is not recoverable
until heating above A_s results in a reversion
15   to austenite. At that point, if the sample is
unrestrained, the original shape will be essentially
completely recovered: if not, it will be recovered to
the extent permitted by the restraint. However, if the
material is then allowed to re-cool to the original
20   temperature at which it was deformed (or a temperature
where SIM behavior of this type is seen), the stress
produced in the sample will be constant regardless
of the strain provided that the strain lies within the
"plateau" region of the stress-strain curve. That is,
25   for a strain between ε_B and ε_A, the stress will be
σ_M. This means that a known, constant force (calculable
from σ_M) can be applied over a wide (up to 5% or more
for certain Ni/Ti alloys) strain range. Thus, though
this resembles the conventional shape memory effect,
30   because the alloy shows SIM and is below A_s a constant
force can be achieved.

In Figure 2, when a stress is applied to the alloy,
it deforms elastically along line OA, then by SIM along
line AB, and by deformation of the martensite to point

C, just as in Figure 1. However, the stress-strain
behavior on unloading is significantly different, since
the alloy is above A_s and the stable phase is therefore
austenite. As the stress is removed, the alloy recovers
5   elastically from C to D; then, at a critical stress,
$_A$, the alloy reverts to austenite without requiring a
change in temperature. Thus reversion occurs at
essentially constant stress. Finally if the stress is
removed from the reverted austenite, it recovers
10   elastically along line EO. The recoverable deform-
ation associated with the formation and reversion of
stress-induced martensite has been referred to as
pseudoelasticity. While $_M$ may be comparatively
high, e.g. 345 MPa (50 ksi) $_A$ is usually subs-
15   tantially lower, e.g. less than 69 MPa (10 ksi) thereby
creating a constant-force spring with an effective
working range of about 5% $(\varepsilon_B - \varepsilon_A)$. The shape
change available in the SMA is thus mechanically,
rather than thermally, actuated and controlled,
20   permitting a greater control over a device incorporating
it.

Suitable alloy for this invention i.e. those displaying
stress-induced martensite at temperatures near mammalian
body temperature (35°-40°C), may be selected from known
25   SMAs by those of ordinary skill in the art, having
regard to this disclosure by tsting for the existence
of the SIM effect at the desired temperature. A
particularly preferred alloy is the nickel/titanium/
vanadium alloy of copending U.S. Patent Application
30   No. 541844, referred to previously.

The invention will now be discussed in detail by some
Examples of the use of an SIM alloy.

Example I.   Heart Valves

Akins, in U.S. Patent No. 4,233,690, the disclosure of
which is incorporated herein by reference, describes
the use of a shape memory alloy ring to hold a sewing
5   cuff to the body of an artifical heart valve. The ring
is made in the austenstic phase, cooled to the martensitic
phase, deformed, placed around the valve body, and
heated or allowed to warm to cause reversion to the
austenitic phase and recovery of the ring into engagement
10   with the valve body.

However, this technique has not found commercial
acceptance. Present medical technique requires that
the valve body be capable of being rotated relative to
the cuff, thereby enabling the surgeon to set the
15   rotational orientation of the valve after it has been
sewn into place. This is desirable because the techniques
used make it difficult to visualize or accomplish
optimal orientation during initial placement.

In order to accomplish the desired torque control to
20   permit the desired rotation and yet ensure a firm hold
of the cuff on the valve body, precise control of the
pressure exerted on the valve body by the ring is
needed. This is difficult because there are substantial
manufacturing tolerances in the valve body which may be
25   made, for example, of pyrolytic graphite or ceramics,
etc. Because the austenite stress-strain curve is
extremely steep, it is not considered practical to use
the simple shape memory technique proposed by Akins.
Indeed, Akins does not even address the issue of
30   rotation of the cuff with respect to the valve body.

However, if an SIM alloy is used instead of conventional
shape memory, the process may be considerably simplified.

First, if the alloy has a stress-strain curve like that
of Figure 1, the alloy ring may be made just as for
Akins. The ring is then expanded from its initial
austenitic state by the formation of SIM. When the
5   ring is placed about the valve body, it needs only to
be heated above A_f and allowed to cool to its original
temperature for the ring to engage the valve body with
a constant force, even if the valve body has a deviation
from the specified size. The torque may thus be
10   controlled to the desired level despite manufacturing
tolerances.

Second, if the alloy has a stress-strain curve like
that of Figure 2, the ring may be expanded, placed over
the valve body, and the stress released all at the same
15   temperature. Because the austenitic phase is stable,
the stress-induced martensite spontaneously reverts to
austenite until recovery is restrained by the ring
engaging the valve body. Because the reversion to
austenite takes place at constant stress, a constant
20   force (and hence constant torque) may be obtained
regardless of manufacturing tolerances. Close temper-
ature control is not required, either; and the fact
that the patient in a heart valve replacement operation
is conventionally cooled as much as 15°C or so below
25   normal body temperature does not affect the operation
of the ring.

To control the torque at a sufficiently low level,
it may be desirable for the alloy ring to be other than
a solid ring, such as, for example, a continuous
30   helical spring, a flat zigzag spring, etc. Such
variations permit the achievement of a greater range of
movement with constant force and a reduction in the
force exerted by the ring on the value body, since the
ring recovers in a bending mode rather than in tension.

Example II. Catheters And Cannulas

Wilson, in U.S. Patent No. 3,890,977, the disclosure
of which is incorporated herein by reference, discloses
a catheter or cannula (both being included hereinafter
5   in the word "catheter") made of, or containing, an SMA
element to cause all or a portion of the catheter to
deploy in a useful form once introduced into a living
body.

However, again this device has not been commercialized.
10   Possible defects of the device which have prevented
commercialization include (i) the inability slowly to
emplace the catheter in a desired position when the
transition temperature of the alloy is below body
temperature (since the SMA element will attempt to
15   revert to its original shape as it reaches body
temperature), thus limiting the ability of the physician
to place the device carefully and precisely; or
alternatively, if the transition temperature of the
alloy is above body temperature, the requirement that
20   the device be heated to a temperature above body
temperature to cause recovery and that the device be
placed so as not to change shape again when it re-cools
(since the body temperature is below the transition
temperature); (ii) the inability to remove the device
25   easily; and (iii) the need for controlled temperature
storage to prevent premature reversion to austenite of
the SMA, with consequent shape change.

The issue of removal of a catheter is especially
significant, and not addressed by Wilson. Consider,
30   for example, a tracheal puncture catheter. This should
be straight for easy insertion into the trachea through

a puncture into the front of the neck, but should curve
after insertion so that the flow of air or oxygen
through the catheter passes axially down the trachea
rather than impinging on the surface of the trachea and

5   damaging it. If a shape memory catheter is used as
contemplated by Wilson, it would presumably become
austenitic and bend after insertion (see Figures 1a and
1b, and corresponding text, of Wilson). But removal
would require either cooling to below the transition

10   temperature (which could easily mean cooling to so low
a temperature that the tracheal tissue is damaged),
removal in the bent shape (presumably damaging tissue),
or forcing the austenitic SMA to straighten to permit
direct removal (unlikely to be satisfactory since the

15   austenitic alloys e.g. of Ni/Ti may have yield strengths
of 690 MPa (100 ksi) or more, and force sufficient to
cause plastic deformation would be required).

If an SIM element is used instead, however, removal can
be accomplished almost as easily as insertion. If the

20   catheter is made in a bent shape (as in Wilson), it can
be straightened by insertion of a straight pin down the
catheter axis, the catheter deforming by the formation
of stress-induced martensite. Insertion of the catheter
into the trachea is accomplished while the catheter is

25   straight, at whatever rate is desired (permitting easy
and accurate placement), and the pin is gradually
withdrawn to permit the catheter to take up its desired
shape as the martensite reverts to austenite. [It is
assumed here that the stress-strain curve of the alloy

30   at the temperature of use is of the form of Figure 2,
so spontaneous reversion occurs on removal of the
stress induced by the pin]. When removal is desired,
it may be achieved simply by the gradual insertion of
the pin, straightening the catheter and permitting easy

35   withdrawal. Insertion of the catheter into the body

and pin removal may, of course, take place simultaneously
if desired, as may pin reinsertion and removal of the
catheter from the body.

Example III.   IUDS

5   Fannon et al., in U.S. Patent No. 3,620,212, the
       disclosure of which is incorporated herein by reference,
       discloses an intrauterine contraceptive device (an IUD)
       proposed to be formed of a shape memory alloy. The
       device is suggested to be deformed in the martensitic

10   phase (the transition temperature being below the
       temperature of the uterus), and the deformed device
       insulated with, e.g., wax and inserted it. Removal is
       contemplated only by using two SMA elements in opposition,
       the higher temperature one being martensitic at body

15   temperature but strong enough so that, if heated, it
       will overcome the lower temperature element and deform
       the IUD back to a removable shape. The heating
       contemplated is electrical. The storage problem
       discussed in Example II also exists here, so that the

20   device must be stored below its transition temperature.

       By the use of an SIM element, however, these dis-
       advantages may be overcome. Again, assume that the
       alloy is SIM psuedoelastic, i.e. that it has the
       stress-strain curve of Figure 2. Then an IUD may be

25   formed into the desired shape in the austenitic state,
       and deformed by compression into a tubular placement
       device (the deformation being such that the strain
       levels lie within the "plateau" of the stress-strain
       curve). When the placement device is inserted into

30   the uterus, the IUD may be deployed by extrusion of the
       IUD from the placement device. Deployment is then
       controlled but immediate, so that the physician may
       satisfy himself with placement. Removal is the reversal

of placement: the placement device is inserted into
the uterus, the IUD deformed by withdrawal into the
placement device, and the placement device withdrawn.
Temperature control is not required.

5   Example IV. Bone Plates

Johnson et al., in U.S. Patent No. 3,786,806, the
disclosure of which is incorporated herein by reference,
propose the use of Ni/Ti SMA bone plates in fracture
fixation. The plate is deformed in its martensitic
10   state, screwed to the two ends of the bone it is
desired to compress together, and warmed (or allowed to
warm) to the austenitic state, when the plate contracts,
compressing the bone ends together.

Because of the high elastic moduli of the austenitic
15   shape memory alloys, it will be difficult to control
the amount of force whch may be applied by a bone plate
of the type proposed by Johnson et al., and precision
placement of the bone ends and elongation of the plate
will be required.

20   If, however, an SIM pseudoelastic bone plate is used,
it will be easily possible to elongate the plate and
fasten it to the bone ends without requiring high
precision. Because of the comparatively large (e.g.
5%) strain range at essentially constant stress, the
25   force which will be put on the bone ends to compress
them will be readily adjustable (by the size of the
plate, for example) and will be insensitive to precise
placement of the bone ends and/or elongation of
the plate. Also, the recovery of the plate, since it
is controlled by mechanical restraint, may be as
30   gradual as desired, achieving excellent force and time
control, and permitting the surgeon to make adjustments
as desired.

Example V.   Marrow Nails

Baumgart et al., in U.S. Patent No. 4,170,990, the
disclosure of which is incorporated herein by reference,
discloses the use of the two-way shape memory effect
5   (where an SMA element exhibits a first shape in the
austenitic state and a second in the martensitic state,
and spontaneously changes between the two shapes with a
change in temperature) in, inter alia, marrow nails
(see Figures 1a through 1e, and corresponding text, of
10   Baumgart et al.).

The method proposed, however, requires the use of a
wide temperature range in order to cause the phase
change which is the origin of the two-way shape memory
effect (5°C to 60°C for the water used to cool or heat
15   the nail). In addition, it requires the manufacture of
two-way shape memory elements, which is generally more
complex than the manufacture of conventional shape
memory elements; and precise control of the tranisition
temperature is required.

20   However, if an SIM pseudoelastic alloy element is
employed, these disadvantages may be overcome. If
internal tangs, which may be gripped by an inserted
tool, are provided within a marrow nail of the type
shown in Figure 1a of Baumgart et al., then the nail
25   may be radially compressed by the application of stress
by such a tool. When the nail is released by the
tool, it will expand to fill the bone channel with a
constant force (not readily available by Baumgart et
al.); and it may be withdrawn by the reverse procedure.

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Example VI. Dental Arch Wire

Andreasen, in U.S. Patent No. 4,037,324, the disclosure
of which is incorporated herein by reference, proposes
the use of dental arch wires made of Ni/Ti alloys
5   instead of conventional 18-8 stainless steel wires.
The wires are stated to be of lower elastic modulus and
higher elastic limit than stainless steel, which is
stated to be advantageous. Heat recovery of an SMA
wire is also suggested as a technique for orthodonture.

10   The technique of using the conventional shape memory
effect is not believed to have found clinical application,
possibly because such a technique would require rapid
placement of the wire in its martensitic state to avoid
premature recovery, and would result in rapid recovery
15   with extremely high forces, which would be painful for
the patient.

The use of a wire which displays lower elastic modulus
and higher elastic limit than stainless steel has found
some application, however. Otsuka et al. in Metals
20   Forum, v. 4, pp. 142-52 (1981) have suggested that this
behavior may be the result of elasticity enhanced by
cold working and martensite-to-martensite psuedoelasticity
in an alloy which has a transition temperature below
body temperature. The alloy, then, is martensitic
25   rather than austenitic in its undeformed state.

While the use of an enhanced elasticity wire may offer
some advantages over the more usual stainless steel
wire, it remains the situation that the amount of
motion in the teeth that may be produced by an arch
30   wire without further adjustment is largely limited
by the pain tolerance of the patient (since the force

is largely limited by the pain tolerance of the patient
applied by the arch wire is proportional to the
deformation of the wire). However, if an SIM pseudoelastic
wire is used, it can exert a relatively constant force
5   (chosen by the dentist to be sufficient to cause tooth
movement but not painful) over a strain range of up to
5%. The load may be applied mechanically, and is thus
more readily established, and no precise temperature
control of the alloy is needed as would be required for
10   the shape memory effect.

Example VII. Coil Stents and Filters

The use of tubular coiled wire stent grafts has been
discussed in the medical literature since 1969.
Although the coils helped maintain patency of the
15   vessels in which they were placed, they were difficult
of insertion unless narrow enough to significantly
narrow the lumen of the vessel. Recently it has been
proposed, see Radiology, v. 147, pp. 259-60 and pp.
261-3 (1983), the disclosures of which are incorporated
20   herein by reference, to use SMA wire to form these
tubular coils. The wire, which has a transformation
temperature below body temperature, is introduced
through a catheter after being straightened in its
martensitic state. When the wire is heated, the coil
25   re-forms.

Because of the difficulty of controlling the trans-
formation temperature accurately, it has proved necessary
to cool the straightened wire during insertion and/or to
heat the wire to form the coil after insertion. These
30   procedures add to the complexity of the operation.

If an SIM pseudoelastic wire is used to form the
coil, which is then isothermally deformed by loading
into a catheter, then the need for temperature control
is avoided. The wire remains straight when in the
5   catheter, but re-forms the coil spontaneously when it
is extruded from the catheter. Accurate placement is
thus readily obtainable, since there is no urgency as
might be required with a conventional shape memory
effect element.

10   It has similarly been proposed to use SMA wire to form
a filter for emplacement by catheter in the vena cava
to trap blood clots. The filter is formed in the
austenitic state, the wire straightened in the
martensitic state and inserted, and the filter re-forms
15   on warming. Just as for the coil stents discussed
above, the use of an SIM pseudoelastic wire would
greatly simplify manufacture and insertion of such a
vena cava filter, permitting accurate placement
with no need for urgency or temperature manipulation.

20   <u>Example VIII.   Bone Staples, Clips, etc.</u>

Bone staples are frequently used to hold fragments of
fractured bone together when the fracture is fixed, and
may be used in some cases as a replacement for bone
plates in the same situation. Sometimes the staples
25   are inserted into drilled holes, sometimes merely
driven into the bone directly.

It would be desirable to have a bone staple which
provided a controlled force between the tines which
would tend to hold the staple in place. Shape memory
30   alloys have been proposed for this application, but
again the problem of accurate placement while operating
quickly enough to prevent the shape change associated
with the martensite-to-austenite transition and/or the

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need for temperature control complicate their use.

If an SIM alloy is used, these disadvantages may be
readily overcome. If the alloy is below A_s, it may
be emplaced in the martensitic state. Brief heating
5   will then be required to cause it to become austenitic,
but on recooling to body temperature, a constant force
can be achieved. If the alloy is above A_s, the
staple can be held deformed by a moderate force, then
released after insertion to also provide an accurately-
10   known force. In either event, removal is easier than
if the alloy is purely austenitic, as discussed
above for Examples II and V, for example.

Similarly, SIM alloy (especially alloy which is
pseudoelastic, above A_s at its utilization temperature)
15   may be used to manufacture vascular clips, etc. The
alloy element here acts as a constant force spring over
a wide strain range (greater than conventional elastic
metals), resulting in ease of use.

From the foregoing, it is clear that, in a situation
20   where narrow temperature differences are available or
preferable, as often is the case in medical applications,
mechanically constrained shape change is-a much more
useful solution than heat actuated shape change. It
offers a degree of control heat actuation does not, it
25   offers easier alloy composition control, it eases
mating part tolerance requirements, and it offers
simple mechanical reversal at minimal stress levels,
all without heating, cooling or insulation complications.

CLAIMS:

1.   A medical device intended for use within a
mammalian body, or in such proximity to a mammalian
body that the device is substantially at body temperature,
which device comprises an alloy element which displays
5   stress-induced martensite at said body temperature.

2.   A device according to claim 1 which is a heart
valve, the alloy element being a ring employed to hold
a sewing cuff onto the valve body.

3.   A device according to claim 1 which is a catheter,
10   the alloy element being the catheter or a part thereof
which causes the catheter to assume a bent shape.

4.   A device according to claim 3 which is a tracheal
catherter.

5.   A device according to claim 1 which is an
15   intrauterine contraceptive device or a bone plate, or a
marrow nail.

6.   A device according to claim 1 which is a dental
arch wire, or a bone staple or a clip.

7. A method of installing a pseudoelastic shape-memory
20   alloy medical device within a mammalian body, or in
such proximity to a mammalian body that the device is
substantially at body temperature wherein the pseudo-
elastic shape-memory alloy medical device displays
reversible stress-induced martensite at body temperature,
25   the method comprising:

deforming the medical device into a deformed shape
different from a final shape, said deforming
occurring by the formation of stress-induced
martensite;

5   restraining the deformed shape of the medical
device by the application of a restraining means;

positioning the medical device and restraining
means within, or in proximity to, the body;

removing the restraining means;

10   isothermally transforming the device from the
deformed shape into the final shape.--

8. A method of installing a medical device within
a mammalian body, or in such proximity to a mammalian
body that the device is substantially at body temperature,
15   the method comprising:

manufacturing the medical device from a
pseudoelastic shape-memory alloy wherein the
pseudoelastic shape-memory alloy medical device
displays reversible stress-induced martensite at
20   body temperature;

deforming the medical device into a deformed shape
different from a final shape, said deforming
occurring by the formation of stress-induced
martensite;

25   restraining the deformed shape of the medical
device by the application of a restraining means;

positioning the medical device and restraining
means within, or in proximity to the body;

removing the restraining means;

isothermally transforming the device from the
5   deformed shape into the final shape.--

9.   A medical device assembly for use within a mammalian
body or in such proximity to a mammalian body that the
medical device is substantially at body temperature,
comprising:

10   a medical device and a restraining means;

        said medical device being made of a pseudoelastic
        shape-memory alloy displaying reversible, stress-
        induced martensite at body temperature;

        said medical device being deformed by the formation
15   of stress-induced martensite into a shape different
        from a final shape and then restrained in the
        deformed shape by said restraining means;

        said medical device and said restraining means
        being positioned in the body whereupon the
20   restraining means is removed and the medical
        device isothermally transforms from the deformed
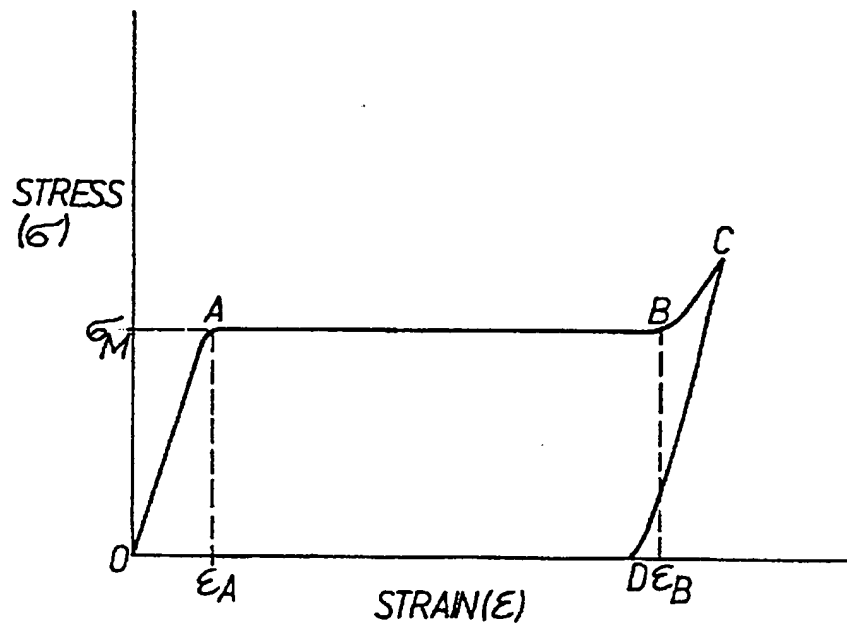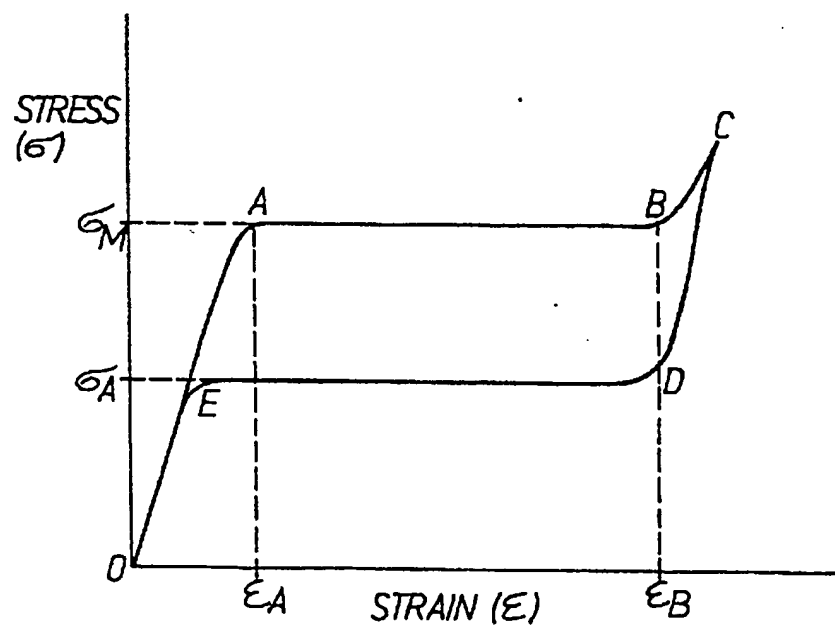   shape into the final shape.

        ****

Fig.1.

Fig.2.